UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CAREDX, INC.	)	
	)	
Plaintiff,	)	C.A. No. 19-662 (CFC)
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
NATERA, INC.,	)	
	)	
Defendant.	)	

CAREDX'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A PERMANENT INJUNCTION

Dated: May 6, 2022

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CareDx respectfully requests that this Court enter a permanent injunction against future false advertising by Natera.

I. INTRODUCTION

After the jury found that nine different Natera advertising claims were false and violated the Lanham Act, Natera represented that it would promptly cease using them and would remove them from its website by the end of the week of March 20, 2022. D.I. 329; *see* Declaration of Edward Reines ("Reines Decl."), Ex. A. Natera did not live up to that commitment. *Id.* CareDx showed Natera that the false advertising claims were still on its website on March 28, 2022, several days after Natera stated they would be removed. *Id.* On March 31, 2022 Natera again committed to remove them from its website and to cease such advertising. *Id.* And it again failed to do so. *Id.* Notwithstanding this, Natera has affirmatively communicated *to physicians that it has removed the claims the Jury found to be false from its website. Id.* Ex. J.

Even today, Natera's website contains the following claims the jury found to be literally false (among others): "Prospera is more sensitive and specific than any other test on the market", "Prospera misses nearly three times fewer rejections than first generation dd-cfDNA", "Lower risk of missing active rejection", and "Unparalleled Precision." *Id.* at Exs. A-I. And a Natera Twitter account makes

claims of use for pediatric patients that the Jury also found to be literally false. *Id.* at Ex. K.

CareDx also asked Natera to formally stipulate it would not use those advertisements. Natera declined, but refused to explain why. *Id.* at Ex. A.

A permanent injunction is therefore warranted and necessary to protect CareDx and the public from Natera's false advertising regarding the performance of its kidney rejection test. CareDx invested years and millions of dollars to create, develop and promote AlloSure—a donor-derived cell-free DNA (dd-cfDNA) assay that revolutionized the standard of care for kidney transplant patients. It invested heavily to educate the transplant community that AlloSure was a tremendous advance relative to the long-existing state of the art. As the Jury's verdict shows, Natera relied on what it knew to be false superiority claims to deceive those same physicians into switching to Prospera.

II. NATURE AND STAGE OF PROCEEDINGS

Pursuant to stipulation and this Court's Order dated March 31, 2022 (D.I. 336), CareDx submits this brief in support of a permanent injunction.[1]

[1] CareDx reserves the right to seek attorneys' fees, pre-judgment interest, and post-judgment interest after judgment is entered in this matter. *See Osterneck v. Ernst & Whinney,* 489 U.S. 169, 175 (1989) ("[A] postjudgment motion for discretionary prejudgment interest constitutes a motion to alter or amend the judgment under Rule 59(e)."); *Axiva Health Sols., Inc. v. Infusion Ctr. of Pennsylvania*, CA No. 21-5313, 2022 WL 1028707 at *2 (E.D. Pa. Apr. 6, 2022) (attorneys' fees only available after

III. SUMMARY OF THE ARGUMENT

CareDx is entitled to a permanent injunction because it has been (1) irreparably harmed, (2) damages are insufficient to compensate CareDx for its injuries, (3) the balance of equities weigh in favor of CareDx, and (4) an injunction is in the public interest. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). Natera's false advertising has irreparably harmed AlloSure's reputation and CareDx's market share and the law recognizes that damages are insufficient to compensate CareDx for these injuries. The balance of equities likewise weighs in favor of CareDx because Natera has continued its unlawful conduct even after the Jury's verdict and repeated representations that it has removed any false statements from its promotional materials. And the public interest will be served by enjoining Natera from continuing to make literally false statements, thereby helping to ensure transplant physicians and patients receive accurate information critical to patient care.

IV. ARGUMENT: CAREDX IS ENTITLED TO A PERMANENT INJUNCTION

Under the Lanham Act, an injunction is a "usual and standard remedy" and "the common historical practice has been that a prevailing plaintiff in a case of . . .

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party has "been awarded some relief *by the court*") (quoting *Buckhannon Bd. & Care Home, Inc. v. W.Va. Dep't of Health and Hum. Res.*, 502 U.S. 598, 603 (2001)).

false advertising will ordinarily receive injunctive relief of some kind." *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F.Supp.2d 384, 479 (D.N.J. 2009) (citing Thomas McCarthy, Trademarks & Unfair Competition § 30:1 (4th ed.2006) and *Lermer Germany GmbH v. Lermer Corp.*, 94 F.3d 1575, 1577 (Fed. Cir. 1996)).

"A plaintiff may obtain a permanent injunction by demonstrating (1) it has suffered an irreparable injury; (2) that remedies at law are inadequate to compensate for that injury; (3) that the balance of hardships favors a remedy in equity; and (4) that the public interest would not be disserved by an injunction." *eBay*, 547 U.S. at 391.

CareDx has established each of these elements. CareDx has suffered, and will continue to suffer, irreparable harm absent an order permanently enjoining Natera from disseminating advertising statements the Jury found to be literally false.

A. Natera's False Statements Have Irreparably Harmed CareDx

CareDx has demonstrated irreparable harm both because it is entitled to a presumption of such harm under the law and because it showed irreparable harm to its reputation and market share.

1. CareDx Is Entitled To A Presumption Of Irreparable Harm

Following the Trademark Modernization Act of 2020, the Lanham Act provides that a prevailing plaintiff seeking a permanent injunction is entitled to a rebuttable presumption of irreparable harm upon a finding of a violation of the Act.

15 U.S.C. § 1116(a); *Lontex Corp. v. Nike, Inc.*, CA No. 18-5623, 2022 WL 622321 at *6 (E.D. Pa. Mar. 3, 2022) (applying the presumption and finding plaintiff entitled to permanent injunction); *Prime Hookah Inc. v. FCM Online LLC*, 2:21-cv-13915(WJM), 2022 WL 1115361 at *4 (D.N.J. Apr. 14, 2022) (same); *see also Trial Lawyers College v. Gerry Spence Trial Lawyers College at Thunderhead Ranch*, 23 F.4th 1262, 1271 (10th Cir. 2022) ("Congress Amended the Lanham Act to expressly allow a presumption of irreparable injury").

Here, the Jury's finding of literal falsity evidences that CareDx met its burden in proving Natera's false statements were material and had a likelihood of deceiving consumers. Jury Instructions ("J.I.") 3.2; *see also Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011). CareDx is therefore entitled to a presumption of irreparable harm.

2. Irreparable Harm To Reputation

Even without this statutory presumption, CareDx has shown irreparable harm to its reputation.

"[I]rreparable injury does not require diversion of actual sales and it can include the loss of control of reputation." *Newborn Bros. Co., Inc. v. Albion Engineering Co.*, 481 F.Supp.3d 312, 359 (D.N.J. 2020) (citing *W.L. Gore & Assocs., Inc. v. Totes Inc.*, 788 F.Supp.800, 810 (D. Del. 1992)). Harm to reputation can be shown by evidence of "literally false, unsubstantiated comparative claims"

and "the competitive relationship between the parties and products." *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 205 (3d Cir. 2014).

Courts have recognized that, where a party "has spent substantial resources for building its reputation as a leader in the field," "[r]epeated claims of competitive superiority made to the same market of consumers will eventually lead to lost sales and deprive [plaintiff] of a legitimate competitive advantage." *W.L. Gore & Assocs.*, 788 F.Supp. at 811. This type of false comparative advertising tarnishes a party's reputation and supports a finding of irreparable harm. *Id.*; *Groupe SEB USA*, 774 F.3d at 204-05 (finding plaintiff established likelihood of irreparable harm where literally false comparative statements referred to plaintiff by name).

Indeed, in the context of pharmaceutical advertising, courts understand that it "will be hard for physicians to 'unhear' [marketing claims] once heard" and have found that allowing a deceptive marketing campaign to continue "is likely to fundamentally alter the existing paradigm . . . in ways that irreparably harm [plaintiff's] reputation and goodwill." *GlaxoSmithKline LLC v. Boehringer Ingelheim Pharms., Inc.* 484 F.Supp.3d 207, 227-28 (E.D. Pa. 2020).

So too here. Natera's literally false advertising has irreparably harmed CareDx's reputation, which CareDx spent years developing. AlloSure changed the standard of care for kidney transplant patients, but it required years of research, sponsored multi-year clinical studies at multiple transplant centers, publication in

peer-reviewed journals, and a significant educational marketing initiative to convince physicians to start using dd-cfDNA technology. Dr. Peter Maag, former CEO of CareDx, explained that the validation study for AlloSure, the DART study, took several years, and CareDx expended significant resources to educate physicians about AlloSure's utility, including more than doubling the size of its field team. 3/7, 201:3-13, 204:5-19; *see also* 3/8, 354:10-15, 354:22-355:14, 356:22-357:9 (CareDx Chief Marketing Officer Sasha King detailing how CareDx worked with physicians to educate them about how AlloSure can be used for patient management); 3/7, 193:12-21 (Maag explaining physicians are "very conservative" and that "in order for them to adopt new technology, you have to be constantly educating them, showing them good data").

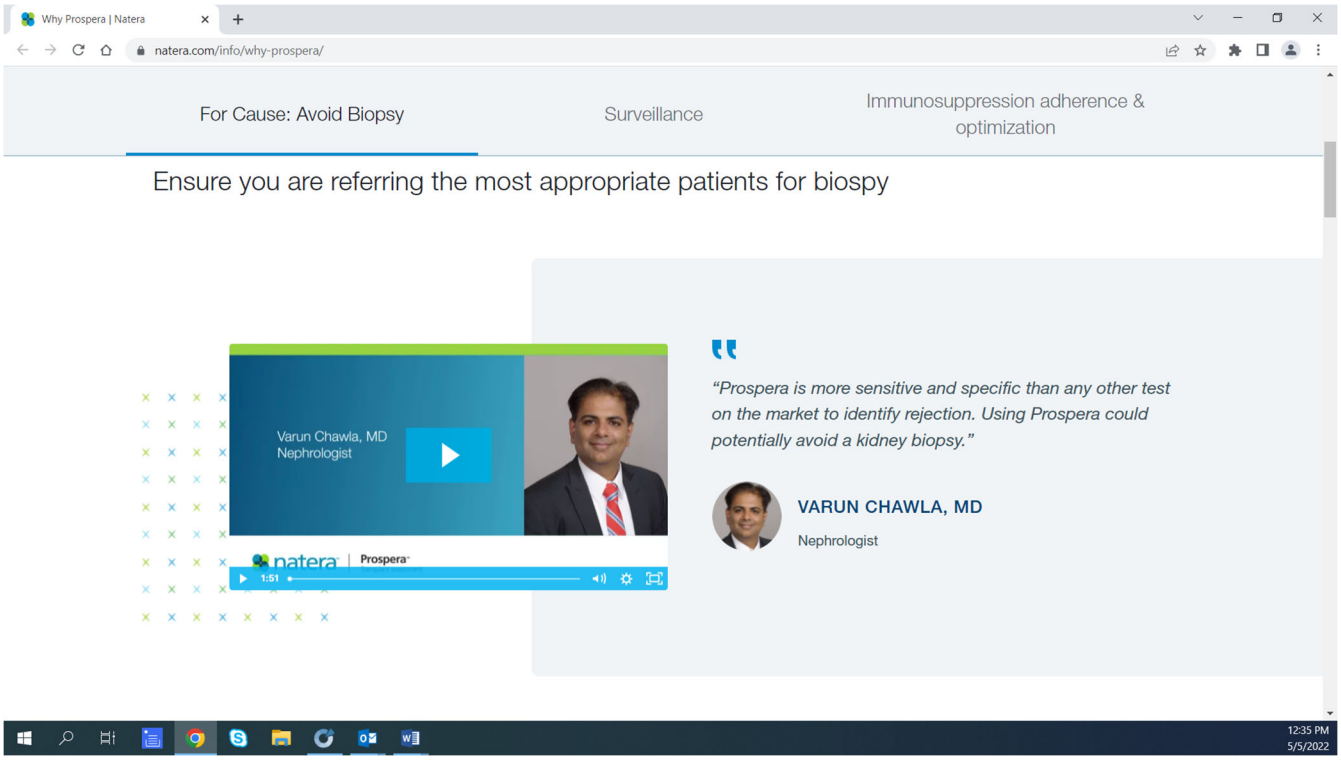
Following several years of effort by CareDx to educate clinicians, Natera began making what the Jury found to be false superiority claims for Prospera, denigrating AlloSure as "first-generation" technology, even though Natera knew that AlloSure and Prospera "are measuring the same analyte using the same method." 3/9, 678:23-679:2. Natera falsely claimed: Prospera is "more sensitive and specific", "Prospera demonstrated better performance in correctly classifying patients with active rejection" than "First-generation dd-cfDNA", Prospera has "higher sensitivity and nearly 18% higher area under the curve (AUC) than the competitive dd-cfDNA assay", "3x fewer rejections missed" than "First generation dd-cfDNA", "Prospera

misses nearly three times fewer rejections than first-generation dd-cfDNA", and "Stronger test performance." D.I. 329; *see also* PTX141-5 ("Positioning Statement": "the need for something better" than "first generation cell-free DNA" and "most optimized cell-free DNA technology to better 'detect'"). Moreover, the evidence showed that Natera was repeatedly exposing clinicians to these claims through transplant site visits, webinars, drip email campaign, dinners with clinicians, presentations at conferences, print materials, its website, and a roadshow. *See, e.g.*, *Id.* at 20-30 (Prospera Marketing Plan).

CareDx saw that Natera's false advertising was causing confusion among clinicians as to the alleged superiority of Prospera and it needed to return to nearly all of the centers it had already educated and explain to them why Prospera is not superior to AlloSure. 3/7, 212:2-10; 3/8, 361:3-362:3. Instead of expanding the market to additional centers, CareDx was forced to continuously defend itself, expanding its salesforce even more to respond to Natera. *Id.*; 3/8, 363:11-21; 379:11-17; 3/7, 219:3-14.

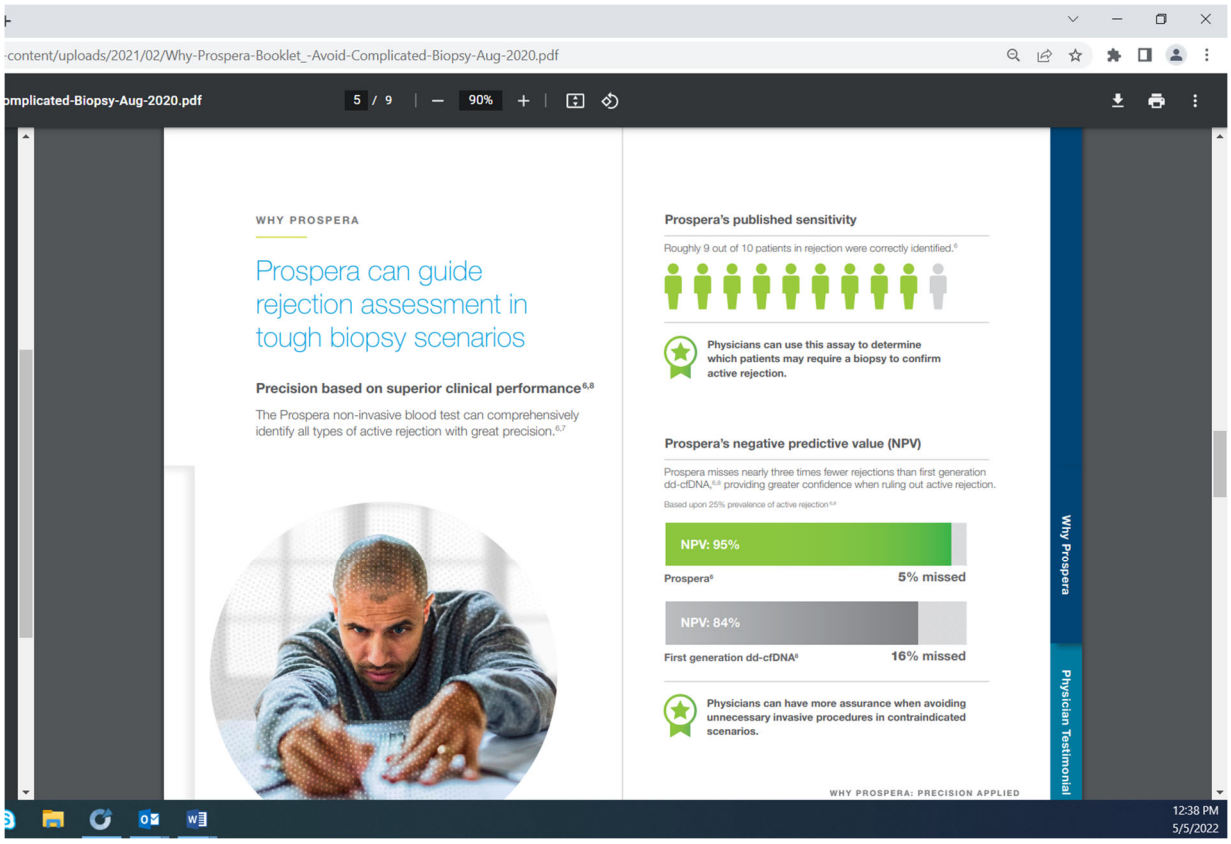
Troublingly, some of the statements the jury found to be literally false are still available on Natera's website. For example:

The Jury found claims that Prospera is "more sensitive and specific" than AlloSure to be false (D.I. 329 (CareDx Question No. 1)), but Natera's website still claims Prospera is "more sensitive and specific than any other test on the market."



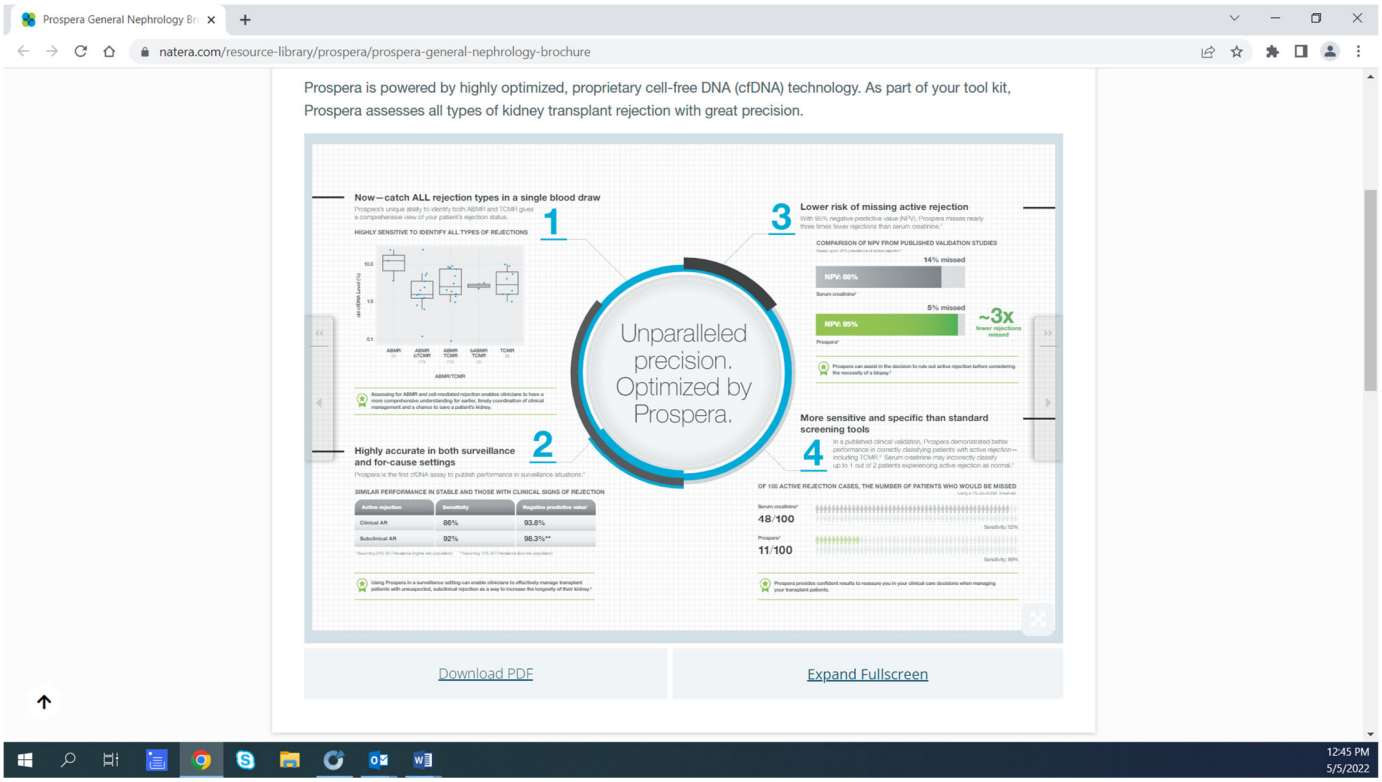
See Reines Decl., Ex. B.

The Jury also found claims that "Prospera misses nearly three times fewer rejections than first generation dd-cfDNA" and a chart comparing the NPVs of AlloSure and Prospera to be false. D.I. 329 (CareDx Question Nos. 5, 6). But Natera still makes both claims on its website:



See Reines Decl., Ex. D.

The Jury further found that claiming "Unparalleled precision" in a circle connected to four key performance metrics is false. D.I. 329 (CareDx Question No. 8). Yet, Natera continues to use the phrase "Unparalleled precision" to describe Prospera.



See Reines Decl., Ex. H

The jury also found that Natera's claim that Prospera could be used with pediatric patients was false. D.I. 329 (CareDx Question No. 10). But Natera's "NateraNeph" Twitter account makes a variation of this same false claim:

See Reines Decl., Ex. K.

That Natera continues to make these false claims may lead physicians and patients to mistakenly believe that these claims are true because they remain available following the Jury's verdict. Indeed, Natera encourages this belief through communications to physicians that it has removed all of the challenged advertisements:

> Natera believes the jury's verdict against us is wrong as a matter of law and has asked the Court to overturn it. This process will take time, and the case is still far from over. With that said, Natera has removed the specific comparison pieces that were in question and will continue to focus on the growing body of peer-reviewed data that supports the quality and performance of the Prospera test.

See Reines Decl., Ex. J.

Absent an injunction, CareDx's reputation will continue to suffer and CareDx will need to keep diverting resources to combat Natera's false claims.

3. Irreparable Harm To Market Share

CareDx has also suffered irreparable harm to its market share. The Third Circuit has found that "loss of market share is a 'potential harm which cannot be addressed by a legal or an equitable remedy following a trial.'" *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.3d 797, 801 (3d Cir. 1989)); *Newborn Bros.*, 481 F.Supp.3d at 360 (ordering a preliminary injunction where defendant's false claims "led to lost sales

and deprived [Plaintiff] of its competitive advantage."); *GlaxoSmithKline LLC*, 484 F.Supp.3d at 227 (crediting expert's testimony that "[t]he equity drained away through brand reputation risk may never be recovered."). In *Merck Eprova AG v. Gnosis S.p.A.*, for example, the court found that plaintiff had met its burden of irreparable harm where (1) the parties were competitors in the same market; and (2) there was a logical connection between defendant's false advertising and plaintiff's sales position. 901 F.Supp.2d 436, 461-462 (S.D.N.Y. 2012).

Here, there should be no question that CareDx and Natera are competitors and that Natera's false advertising affects CareDx's market position. First, the undisputed evidence establishes that the "biggest competitor for Natera's assay is CareDx's AlloSure." 3/9, 620:18-621:8 (Natera's Medical Director Dr. Gauthier); *see also* 3/8, 378:10-14 (King testifying that Natera is competition). Moreover, the unrebutted evidence at trial established that Natera's goal was to convert AlloSure users to Prospera. PTX310-4 ("key is to clearly differentiate this new and better test from the entrenched competitor, with a business objective of converting Allo[S]ure customers to Prospera.") 3/9, 621:19-622:4 (Dr. Gauthier admitting Natera targeted CareDx's customers with performance claims); 3/8, 579:18-20 (Director of Marketing Shephalie Lahri conceding Prospera's goal was to convert AlloSure users); PTX141-3 (identifying "CONVERT ALLOSURE USERS TO PROSPERA USERS" as goal of "Prospera Marketing Plan").

Importantly, the evidence showed that Natera succeeded in diverting sales. 3/7, 212:4-12, 220:5-221:3 (Maag providing three specific examples of major centers in which CareDx lost sales); DTX655 (Natera's Prospera sales). CareDx's damages expert, Mr. James Malackowski testified that, "in a but-for world, without the alleged false advertising, the demand for the units at issue would have stayed with CareDx." 3/10, 1024:25-1025:4. Such a loss of market share constitutes irreparable harm. *See Novartis*, 290 F.3d at 596 ("We are satisfied this loss of market share constitutes irreparable harm.").

B. Remedies At Law Are Inadequate To Compensate CareDx

CareDx has also established the second factor necessary for injunctive relief—the damages awarded in this case cannot adequately compensate CareDx for the damage to its reputation and the reputation of AlloSure. *eBay*, 547 U.S. at 391.

Courts have consistently held that reputational loss, such as that suffered by CareDx, cannot be compensated by remedies at law including damages awards. *See, e.g.*, *United States Soo Bahk Do Moo Duk Kwan Fed'n, Inc. v. Tang Soo Karate School, Inc.*, No. 3:12-CV-00669, 2015 WL 4920306, at *32 (M.D. Pa. Aug. 17, 2015) ("loss of control of reputation, loss of trade, and loss of good will are harms of a peculiar nature, so that compensation in money cannot atone for them.") (quotations omitted) (quoting *Opticians Ass'n of America v. Independent Opticians of America*, 920 F.2d 187, 195 (3d Cir. 1990)); *Coach, Inc. v. Ocean Point Gifts*,

No. 09-4125 (JBS), 2010 WL 2521444, at *9 (D.N.J. 2010) ("While a remedy at law would provide a degree of monetary relief, it will not compensate for the injury to [plaintiff's] reputation").

Courts recognize that money cannot undo damage to a reputation or a loss in market share, and does not protect against future unlawful conduct. *Novartis*, 290 F.3d at 596 ("loss of market share is a potential harm which cannot be redressed by a legal or equitable remedy following a trial") (internal citation omitted); *Gnosis S.p.A.*, 901 F.Supp.2d at 462; *see also United States Soo Bahk Do Moo Duk Kwan Fed'n*, 2015 WL 4920306, at *32 ("an injunction would also protect the Plaintiff against *future* infringement, which money damages cannot do") (emphasis in original); *Merck Eprova AG v. Brookstone Pharms., LLC*, 920 F.Supp.2d 404, 432 (S.D.N.Y. 2013) ("damages cannot compensate [Plaintiff] for the enviable market position—and the corresponding decline in its own market position—that [Defendant] has acquired thanks to its false advertising.").

C. Absence Of An Injunction Exceeds Any Potential Harm To Natera

In deciding whether injunctive relief is appropriate, the Court must also balance the hardships to the respective parties. *See Opticians Ass'n*, 920 F.2d at 197. In making this determination, the Third Circuit has held that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." *Novartis*, 290 F.3d at 596.

Here, potential harm to CareDx in the absence of injunction greatly exceeds any potential harm to Natera. First, there is a real risk that Natera will again engage in false advertising. Natera's conduct was brazen and willful. It has twice represented it would remove the offending materials and failed to do so. And it has refused to stipulate to the removal of these materials without explanation. *See* Reines Decl., Ex. A.

Second, any harm to Natera is of its own making, particularly because the Jury found that Natera willfully engaged in a false advertising campaign (D.I. 329, Question No. 11). *See Opticians Ass'n*, 920 F.2d at 197 (finding grant of injunction would impose no greater harm on defendant where defendant's conduct was intentional); *U.S. v. Marine Shale Processors*, 81 F.3d 1329, 1359 (5th Cir. 1996) ("a court need not balance the hardship when a defendant's conduct has been willful.") (citing *United States v. Pozgai*, 999 F.2d 719, 636 (3d Cir. 1993)).

Third, Natera's counsel has twice represented that Natera has taken down all of the statements found by the Jury to be false advertising claims and it does not plan to use them. *See* Reines Decl., Ex. A. Thus, an injunction will not result in harm to Natera. *Newborn Bros.*, 481 F.Supp.3d at 360-61 (finding permanent injunction will not result in greater harm to defendant where defendant had already ceased most allegedly false advertising).

Finally, the requested injunction is narrowly tailored to prevent Natera only from making statements the Jury found to be literally false. Natera will not be enjoined from advertising Prospera in an accurate, truthful manner.

D. An Injunction Is In the Public Interest

"In cases of false advertising claims, 'the public has a right to information that will allow them to assess the quality of a product and to accurately price the product in accordance with their priorities and desires.'" *Newborn Bros.*, 481 F.Supp.3d at 359 (quoting *W.L. Gore*, 788 F.Supp. at 813)). The Third Circuit has held that "public interest . . . is a synonym for the right of the public to not be deceived or confused." *Shields v. Zucarrini*, 254 F.3d 476, 486 (3d Cir. 2001) (citing *Opticians Ass'n*, 920 F.2d at 197)). Here, there is a strong public interest in protecting the transplant community from the confusion and deception of Natera's false claims.

The public interest in enjoining Natera's false statements is particularly apparent here, where Natera's false claims implicate patients' health and safety. *See GlaxoSmithKline*, 484 F.Supp.3d at 228 (finding an injunction that enjoins defendant "from making false and misleading statements not supported by scientific studies" protects the health and safety of patients and is in the public interest); *see also*, *Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d 187, 193 (2d Cir. 1996) ("the public's interest is especially significant when health and safety concerns are implicated"); *Morgenstern Chemical Co. v. G.D. Searle & Co.*, 253 F.2d 390, 393 (3d Cir. 1958)

("In the field of medical products, it is particularly important that great care be taken to prevent any possibility of confusion."). Dr. Maag testified that transplant patients are the most vulnerable patients. 3/7, 186:5-14. Such patients and their physicians are entitled to truthful advertising, to ensure they get the best, and safest, care available.

CareDx respectfully requests the Court to enter an injunction in the form provided in its motion.

V. CONCLUSION

CareDx respectfully requests that the Court enjoin Natera from disseminating any of the statements the Jury found to be literally false, as provided in CareDx's motion.

Dated: May 6, 2022

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order for All Cases. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 3,415 words, excluding the case caption, signature block, table of contents and table of authorities.

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Dated: May 6, 2022